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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/844,731	04/21/1997	STALEY A. BROD	D5716-CIP3	7636

27851 7590 06/13/2005

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EXAMINER
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SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/844,731	<b>Applicant(s)</b> BROD, STALEY A.	
	<b>Examiner</b> Jegatheesan Seharaseyon, Ph.D	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,9,11,16,17,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 8,9,11,16,17,19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/14/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

*nd*

### **DETAILED ACTION**

1. This office action is in response to the amendment and response filed on 3/14/05.

Applicant has cancelled claims 1-14. Claims 8, 16 and 19 have been amended. Claims 10, 18 and 21 have been cancelled. Thus, claims 8-9, 11, 16-17 and 19-20 are under consideration.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 8-11 and 16-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. Specifically, Applicant has pointed out in the specification what an "at risk population" is.

#### ***Claim Rejections - 35 USC § 102***

4. The rejection of claims 8, 9, 11, 16, 17, 19, 20 and 22 under 35 U.S.C. 102(e) as being anticipated by Sobel (U.S. Patent No: 5,780,021) is withdrawn because Sobel does describe the recited dosages of the instant invention.

5. New Rejections necessitated by Applicants amendments.

#### ***Claim Rejections - 35 USC § 103***

6. The rejection of claims 10, 18 and 21 under 35 U.S.C. 103(a) as being unpatentable over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 497, 795) is withdrawn in favor of the rejection of claims 8-9, 11, 16-17 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over

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Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 462, 985).

The rejection is withdrawn because Applicant has elected to cancel the claims. Sobel's teachings have been discussed in paragraph 2 of 03/08/2004 Office Action and above in paragraph 6 of 11/29/2004. The reference does not teach dosage ranges described in claims 8,16 and 19. Cummings describes the administration of about 10 to 1,000 units per kg of body weight (see claim 7). Based on the body weight of 87 Kg (males) or 75 Kg (females) provided by the Applicant, this translates to 870 to 87,000 units or 750 to 75,000 units of interferon. This covers the dosage range recited in the claims 8, 16 and 19. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the interferon doses of Sobel to those taught by Cummings with expectation of treating IDMM patients. One of ordinary skill in the art would have been motivated to use interferon in the doses recommended by Cummings et al to treat IDMM with the expectation of success as because Cummings (U.S. Patent No: 5, 019, 382) teaches the treatment of autoimmune disorder, which includes IDMM. Therefore, the instant claims are *prima facie* obvious over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 497, 795).

7. No Claims are allowable.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

#### **Contact information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 06/05

  
JANET ANDRES  
PRIMARY EXAMINER